



MAR 26 2013

510(k) Summary: [As required by 21 CFR 807.92]**AngioDynamics VenaCure EVLT NeverTouch Direct Procedure Kit**

Date Prepared: 08 March 2013

- A. Sponsor: AngioDynamics, Inc.
603 Queensbury Avenue
Queensbury, NY 12804
- B. Contact: Teri Juckett
Regulatory Affairs Manager
Phone: 518-795-1142
- C. Device Name: Trade Name: AngioDynamics VenaCure EVLT NeverTouch
Direct Procedure Kit
Common/Usual Name: Greater Saphenous Vein Procedure Kit
Classification Name: Laser Instrument, Surgical Powered
- D. Classification: Class: Class II
Product Code: GEX
Regulation Number: 21 CFR 878.4810
- E. Predicate Device: Predicate Name: AngioDynamics VenaCure EVLT NeverTouch
Direct Procedure Kit
Predicate 510(k): K112600
Panel: General & Plastic Surgery

F. Device Description:

AngioDynamics VenaCure EVLT NeverTouch Direct Procedure Kits are offered with the following components:

- 600µm Fiber with markings on the fiber to aid in withdrawal
- Introducer Sheath and Dilator
- Entry Needle
- Guidewire

G. Intended Use:

The AngioDynamics, Inc. VenaCure EVLT NeverTouch Direct Procedure Kit is indicated for endovascular coagulation of the great saphenous vein in patients with superficial vein reflux, for the treatment of varicose veins and varicosities associated with superficial reflux

of the great saphenous vein, and for the treatment of incompetence and reflux of superficial veins of the lower extremity.

H. Technological Characteristics:

The proposed device has similar materials, design, components, and technical characteristics as the predicate device.

I. Performance Data:

The proposed AngioDynamics VenaCure EVLT NeverTouch Direct procedure kit is substantially equivalent to the specified predicate device based on a comparison of technological characteristics and the results of non-clinical performance testing in accordance with ISO 10993 and in-house test criteria, which included:

- Fiber to Tip Tensile
- Fiber to SMA Tensile
- Fiber output Testing
- Surface Visual
- Depth Marks
- Simulated Use Testing
- Biocompatibility per ISO 10993-1

J. Conclusion:

The results of the non-clinical testing and a comparison of similarities and differences demonstrate that the proposed and predicate devices are substantially equivalent.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Angiodynamics, Incorporated
% Ms. Teri Juckett
Regulatory Affairs Manager
603 Queensbury Avenue
Queensbury, New York 12804

March 26, 2013

Re: K130671

Trade/Device Name: AngioDynamics, Inc. VenaCure EVLT NeverTouch Direct Procedure
Kit

Regulation Number: 21 CFR 878.4810

Regulation Name: Laser surgical instrument for use in general and plastic surgery and in
dermatology

Regulatory Class: Class II

Product Code: GEX

Dated: March 08, 2013

Received: March 12, 2013

Dear Ms. Juckett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours, FOR

Peter  -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Application: Special 510(k) Submission

Device Name: AngioDynamics, Inc. VenaCure EVLT NeverTouch Direct Procedure Kit

Indications for Use:


The AngioDynamics, Inc. VenaCure EVLT NeverTouch Direct Procedure Kit is indicated for endovascular coagulation of the great saphenous vein in patients with superficial vein reflux, for the treatment of varicose veins and varicosities associated with superficial reflux of the great saphenous vein, and for the treatment of incompetence and reflux of superficial veins of the lower extremity.

Prescription Use X
(Per 21 CFR 801.109)

OR Over-the-Counter Use

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden 
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(Division Sign-Off) for MXM
Division of Surgical Devices
510(k) Number K130671